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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/784,478	02/23/2004	Paul Haefner	GUID.606PA	1794
51294	7590	06/08/2006	EXAMINER	
HOLLINGSWORTH & FUNK, LLC 8009 34TH AVE S. SUITE 125 MINNEAPOLIS, MN 55425			KAHELIN, MICHAEL WILLIAM	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 06/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/784,478		HAEFNER, PAUL	
	Examiner		Art Unit	
	Michael Kahelin		3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 and 30-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 and 30-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Cancellation of claims 20-29 and 37-48 is acknowledged.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 4, 7-11, 16-18, 30, 32-34, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Albrecht et al. (US 5,704,365 hereinafter "Albrecht") in view of Turcott (US 6,409,675 hereinafter "Turcott"). Albrecht discloses the essential features of the claimed invention including:

4. In regards to claims 1 and 30, Albrecht discloses detecting a composite electrical signal (abstract and col. 2, line 20), receiving information related to a non-electrophysiological source (col. 30, line 42), separating a signal from the composite signal (col. 4, line 30), and identifying the signal as a cardiac signal based on the signal and the non-electrophysiological information.

5. In regards to claim 8, the information is pulse pressure information (col. 30, line 51).

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6. In regards to claims 11, 32 and 33, a detection window is provided (210) with a start time (col. 14, line 27).

7. In regards to claim 36, cardiac rhythms are discriminated (col. 13, line 44).

8. Albrecht does not disclose detecting the signals in a subcutaneous non-intrathoracic location, sensing acoustic information, sensing blood flow information, sensing pulse oximetry information, sensing transthoracic impedance, detecting a cardiac condition using the separated signal, detecting a cardiac condition using a correlation between the separated signal and the other signal, and detecting arrhythmia using the signal. Turcott teaches of detecting signals in a subcutaneous intrathoracic location to avoid invasive intravascular surgery (col. 3, line 6), sensing acoustic information (which is blood flow information) to provide information of the heart's mechanical performance (col. 16, line 9), sensing pulse oximetry information to provide pulmonary information (abstract), sensing transthoracic impedance to determine breathing patterns (abstract), and detecting arrhythmia (via heart rate variability analysis) using the separated signal and a correlation between the separated signal and a non-electrical source to accurately diagnose heart abnormalities (col. 7, line 33).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Albrecht's invention by detecting signals in a subcutaneous intrathoracic location to avoid invasive intravascular surgery, sensing acoustic information (which is blood flow information) to provide information of the heart's mechanical performance, sensing pulse oximetry information to provide pulmonary information, sensing transthoracic impedance to determine breathing

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patterns, and detecting arrhythmia (via heart rate variability analysis) using the separated signal and a correlation between the separated signal and a non-electrical source to accurately diagnose heart abnormalities.

9. Claim 2, 3, 5, 6, 12, 13, 19, 31, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Albrecht in view of Turcott, as applied to claim 1 above, and further in view of Corbucci (US 6,792,308 hereinafter "Corbucci"). The modified invention of Albrecht discloses the essential features of the claimed invention except for providing a window defined by the non-electrical signal, detecting a QRS complex within the window, utilizing the temporal location of the peak heart sound, defining the start of detection window based in a time preceding the peak heart sound, determining a time separation between a peak of the separated signal and a peak of the non-electrical signal, and treating arrhythmia. Corbucci teaches of defining a window with heart sounds (PEI+ET, Fig. 5) to electrical activity in comparison to electrical activity, detecting a QRS complex within the detection window (152) to accurately determine time intervals between electrical activity and sounds, utilizing the temporal location of the peak heart sound (s1) to accurately determine intervals between sounds and electrical activity, defining the start of detection window based on a time preceding the peak heart sound (PEI) to calculate the myocardial performance, determining a time separation between a peak of the separated signal and a peak of the non-electrical signal (PEI) to determine the degree of heart failure, and treating arrhythmia (143) to prevent heart stoppage. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the modified invention of

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Albrecht by defining a window with heart sounds to electrical activity in comparison to electrical activity, detecting a QRS complex within the detection window to accurately determine time intervals between electrical activity and sounds, utilizing the temporal location of the peak heart sound to accurately determine intervals between sounds and electrical activity, defining the start of detection window based on a time preceding the peak heart sound to calculate the myocardial performance, determining a time separation between a peak of the separated signal and a peak of the non-electrical signal to determine the degree of heart failure, and treating arrhythmia to prevent heart stoppage.

10. Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Albrecht in view of Turcott, as applied to claim 1 above, and further in view of Wells (US 2003/0032889 hereinafter "Wells"). The modified invention of Albrecht discloses the essential features of the claimed invention except for separating signals using blind source separation and independent component analysis. Wells teaches of identifying constituent signals using blind source separation and independent component analysis (par. 0007) to separate signals where little is know of their individual contributions. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the modify the modified invention of Albrecht by identifying constituent signals using blind source separation and independent component analysis to separate signals where little is know of their individual contributions.

Response to Arguments

11. Applicant's arguments filed 4/10/2006 have been fully considered but they are not persuasive. Applicant argued that the Albrecht and Turcott combination are lacking each and every element of independent claims 1 and 30 because Albrecht assumes and never questions that the sensed signals are ECG signals, but only reduces noise in the signal. However, the claim language does not require questioning whether a signal is a cardiac signal, but only "identifying the separated signal as a cardiac signal".

Albrecht discloses that, "the desired output signal is the ECG signal" (col. 5, line 62). Therefore, the output (separated) signal is identified as a cardiac signal because the algorithm recognizes that the output is the ECG signal.

12. Further, Applicant argued that the secondary signal used by Albrecht is not a non-electrophysiological signal because it relates to the impedance of an electrode. Although the impedance of the electrodes may be an electrical signal, it is not an electrophysiological signal because it is not electrical activity associated with a body part, but only a signal related to the change in an applied voltage. Additionally, claim 10 of the instant Application recites transthoracic impedance as a non-electrophysiological signal, as does Albrecht at column 7, line 9. Lastly, as noted in the previous Office Action, column 30, line 48 Albrecht discloses that other, non-electrical signals may be used in addition to the impedance signal.

13. Further, Applicant argued that, taken as a whole, Albrecht is lacking contextual similarity to Applicant's invention. Specifically in regards to independent claims 1 and 30, Albrecht's disclosure is lacking only subcutaneous electrodes. Due to the prolific

examples of subcutaneous electrodes in the prior art, one having ordinary skill in the art at the time the invention was made would have easily applied Albrecht's teaching of separating an electrophysiological cardiac signal from a non-electrophysiological signal to a subcutaneous electrode configuration to allow implanted devices to utilize the technique disclosed by Albrecht.

Conclusion

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

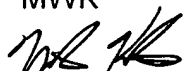
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Kahelin whose telephone number is (571) 272-8688. The examiner can normally be reached on M-F, 9-5.

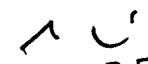
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MWK


6/1/06


GEORGE R. EVANISKO
PRIMARY EXAMINER
6/1/06